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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,480	03/12/2001	Michael P. Maher	AUROBIO.026DV1	1223

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EXAMINER

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
1646	

1646

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

<b>Application No.</b> 09/804,480	<b>Applicant(s)</b> MAHER ET AL.	
<b>Examiner</b> Joseph F. Murphy	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on 15 September 2005.
- 2a)  This action is **FINAL**.
- 2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4)  Claim(s) 1-8 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 1-8 is/are rejected.
- 7)  Claim(s) \_\_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 09/21/2005
- 4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

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## DETAILED ACTION

### *Formal Matters*

Claims 1-8 are pending and under consideration.

### *Response to Arguments*

Applicant's arguments filed 9/15/2005 have been fully considered but they are not persuasive for the reasons set forth below.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Gonzalez et al. (1999), in view of Tung et al. (1992), for reasons of record set forth in the Office Action of 6/13/2005.

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The claims are drawn to methods of characterizing the activity of compounds by addition of the compounds to wells containing cells, applying a biphasic electric field to vary the  $T_m$  of the cells, and monitoring the change in the  $T_m$  by means of a FRET based voltage sensor. The claims are not patentable because Gonzalez teaches a high-throughput screening method wherein cells are added to a microtiter plate, and electrical stimulation can be used for rapid and repetitive stimulation in the microtiter plates, using electrode array technology to apply the stimulus (page 437, first column first full paragraph). The Gonzalez reference further teaches that the method can be used to measure the effects of compounds on state dependent blockers of  $K^+$  or  $Na^+$  channels. The Gonzalez reference does not teach the biphasic stimulus protocol. However, Tung et al. discloses comparison of the effects of biphasic and monophasic electric fields on the electrical stimulation of cardiac cells (abstract). It was noted that "strength-duration curves derived from field stimulation show that over a wide range of pulse durations, biphasic waveforms can recruit and activate membrane patches about as effectively as can monophasic waveforms having the same total pulse duration" (abstract). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to practice the screening method with biphasic electric fields instead of monophasic electric fields. One of ordinary skill in the art would have been motivated to make this substitution in order to have stimulated the cells with a reasonable expectation of success.

Applicant argues that Tung teaches a simulation of biphasic rectangular pulse applied to cardiac muscle cells in order to simulate the effect of such a pulse during electrical defibrillation of the heart. Tung does not teach applying a series of such pulses. Rather, Tung teaches applying only a single biphasic pulse. However, the Tung reference was not cited to teach a series of

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pulses, the Gonzalez reference teaches that electrical stimulation can be used for rapid and repetitive stimulation in the microtiter plates, using electrode array technology to apply the stimulus. Applicant further argues that Gonzalez teaches traditional voltage clamping, e.g., using a patch clamp technique with voltage steps and cites Gonzales, page 434, column 2 and caption for Figure 2. However, the Gonzalez reference teaches a system for a FRET based high throughput screening (see page 437, Figure 4), not only voltage clamping using the patch clamp technique. In addition, Applicants argue that there is no motivation to combine Gonzalez with Tung, however, the motivation is provided in the Gonzalez reference which teaches that methods of using a system for a FRET based high throughput screening can be used for screening of state-dependent blockers of Na<sup>+</sup> and K<sup>+</sup> channels as therapies for epilepsy, pain or cardiac arrhythmia (Gonzalez at 437, column 1, third paragraph).

### *Conclusion*

Claims 1-8 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Murphy whose telephone number is (571) 272-0877. The examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (571) 272-0829.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph F. Murphy, Ph. D.  
Primary Examiner  
Art Unit 1646  
November 15, 2005



**JOSEPH MURPHY  
PATENT EXAMINER**